Output Display Standard: A New Equipment Feature

William D. O'Brien, Jr., PhD
Professor
Department of Electrical and Computer Engineering
University of Illinois
1406 West Green Street
Urbana, IL 61801
Output Display Standard: A New Equipment Feature

William D. O’Brien, Jr., Ph. D.
Department of Electrical and Computer Engineering
University of Illinois
1406 West Green Street
Urbana, IL 61801

ABSTRACT

Did you ever want to increase the frequency of your ultrasound system slightly to get that added diagnostic capability to obtain the benefit of improved resolution? And, did you find that when you increased the frequency, you could not get the penetration depth desired? Well, that all occurred because your diagnostic ultrasound system’s output is regulated and cannot exceed prescribed FDA limits. The Output Display Standard (ODS) (officially titled: Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment) could change this substantially. With the implementation of the ODS, diagnostic ultrasound systems could have a higher output limit, but with these higher limits (and benefits) come the potential for increased risk to the patient. The ODS provides for an output display which gives the user information about the potential for temperature increase (the Thermal Index) and mechanical damage (the Mechanical Index). The objective of the course will be to acquaint you with the potential for added diagnostic benefits and the interpretation of the two indices.

MOTIVATION

The classical engineering trade-off of diagnostic ultrasound instrumentation is that between resolution and the depth of the image (or penetration). Both are directly affected by the ultrasonic frequency. As frequency is increased, resolution improves and penetration decreases. Resolution improves because the ultrasonic wavelength in tissue decreases (becomes a smaller number). Wavelength is inversely related to frequency; increase one and the other decreases.

As frequency increases, the ultrasonic attenuation also increases. Penetration is directly affected by tissue attenuation coefficient which, in turn, is linearly related to frequency. At an ultrasonic frequency of 1 MHz, the attenuation coefficient is approximately 0.7 dB/cm whereas at 2 MHz, it is 1.4 dB/cm. Thus, attenuation coefficient is directly related to frequency; increase one and the other increases. It can be expressed mathematically by the expression 0.7 dB/cm-MHz. Note that at a frequency of 7.5 MHz, the attenuation coefficient is 5.3 dB/cm.

This means that as the ultrasound frequency is increased, and resolution is improved (why resolution improves at higher frequencies is discussed next), penetration is decreased unless it is possible to increase the system’s output in order to compensate for the increased attenuation.

Resolution is the ability to image or resolve discrete structures. In the case of diagnostic ultrasound instrumentation, the structures must be resolved in the image. Resolution is determined by many components and properties of the instrumentation and patient including transducer type, geometry and frequency; receiving and processing electronics; video monitor; and tissue attenuation and sound speed. For simplicity, it is easier to understand resolution by considering two types of resolution, viz., axial resolution and lateral resolution.

Axial resolution (also termed range resolution or depth resolution) is the ability to resolve discrete structures along the beam axis. Quantitatively, it is represented as the minimum distance between two structures at different ranges at which both can just be discretely identified as two separate structures. The best axial resolution is represented by the expression

$$\text{best axial resolution} = \frac{SPL}{2} \quad (1)$$

where SPL, the spatial pulse length, is the space occupied by a single pulse and is directly related to wavelength, $\lambda$, by the expression
\[ SPL = N \lambda \]  
\[ \text{where } N \text{ is the number of cycles per pulse.} \]

Therefore, the **best axial resolution** is

\[ \text{best axial resolution} = \frac{N \lambda}{2} = \frac{N c}{2 f} \]  
\[ \text{where } \lambda = c/f, c \text{ is the propagation speed and } f \text{ is the ultrasound frequency.} \]

The transducer design affects the minimum number of cycles. More highly damped transducers (also referred to as low-\( Q \) transducers) produce very few cycles of sound when shock excited by the pulser voltage. As a **rule of thumb**, there are \( Q/2 \) cycles of pressure contained in the pulse, that is, \( N = Q/2 \), which yields

\[ \text{best axial resolution} = \frac{Q c}{4 f} \]  
\[ \text{If } N = 3 \ (Q = 6), \text{ at ultrasonic frequencies of } 3.5 \text{ MHz (} \lambda = 0.44 \text{ mm) and } 7.5 \text{ MHz (} \lambda = 0.21 \text{ mm), the best axial resolutions are calculate to be } 0.67 \text{ mm and } 0.32 \text{ mm, respectively. Note that as the frequency increases, and other quantities remain constant, axial resolution improves.} \]

The term "best axial resolution" has been utilized because, in practice, the receiving and processing electronics affect axial resolution as does the quality of the monitor. The electronics and monitor are often lumped into the term "system \( Q \)." Low-valued system \( Q \) 's provide better axial resolution than do high-valued ones. Recall that the **quality factor \( Q \)** is defined as the ratio of the center frequency, \( f \), to the system bandwidth, \( \Delta f \), that is,

\[ Q = \frac{f}{\Delta f} \]  
\[ \text{which yields} \]

\[ \text{best axial resolution} = \frac{Q c}{4 f} = \frac{c}{4 \Delta f} \]  
Note that this expression suggests that the **best axial resolution** is a function of only the system bandwidth, \( \Delta f \), since the propagation speed, \( c \), is essentially the same for all patients, that is, 1540 m/s. Substituting the value of the propagation speed yields

\[ \text{best axial resolution} = \frac{0.77}{\Delta f} \]  
\[ \text{where the best axial resolution is in millimeters and } \Delta f \text{ is in MHz.} \]

However, ultrasound images are speckle images and therefore a more representative expression for axial resolution is in terms of the axial length of the pulse, that is,

\[ FWHM_A = \frac{1.37}{\Delta f} \]  
\[ \text{where } FWHM_A \text{ is the full width half maximum length of the pulse in millimeters and } \Delta f \text{ is in MHz. This expression is also only a function of the system bandwidth but yields a numerical value for axial resolution about 1.8 times greater than the best axial resolution. Thus, the axial resolution improves (its numerical value decreases) when the bandwidth increases. It turns out that as the frequency is increased, the bandwidth also increases which results in improved axial resolution.} \]

**Lateral resolution** is the ability to resolve discrete structures perpendicular to the beam axis. Quantitatively, it is represented as the minimum distance between two side-by-side structures at the same range at which both can just be discretely identified as two separate structures. The **best lateral resolution** is represented by the expression

\[ \text{best lateral resolution} = \min \text{ beam width.} \]  

The "best lateral resolution" term is employed here for the same reasons that the term "best axial resolution" was used.

When an ultrasonic field is focused, the focal range occurs in the near field of the transducer. For a long focus case, the minimum beam width is greater than that for the short focus case. Without getting too mathematically, the beam width at the focus is directly proportional to wavelength (\( \lambda \)) and focal length (\( L \)) and is inversely proportional to the transducer diameter (\( d \)), that is,
best lateral beam width at focus =

\[ FWHM_L = \frac{\lambda L}{a}. \] (10)

where \( FWHM_L \) is the full width half maximum of the focal region. When the wavelength \( \lambda \) remains constant, the best lateral beam width at the focus improves as focal length, \( L \), decreases. Another way to improve lateral resolution at the focus is to decrease the wavelength (increase frequency).

Therefore, lateral resolution is affected by the wavelength, transducer size and geometry (focusing), and focal range. As lateral resolution improves, the wavelength decreases (frequency increases), transducer size increases and the focal range decreases. Away from the focal range axially, the lateral resolution quickly deteriorates.

In summary, the best possible resolution is always an important goal. In general, resolution improves when frequency increases. However, depth of penetration is decreased. To compensate for the decreased depth of penetration, the system output can be increased. With this increased system output comes the increased possibility of an unwanted biological effect. Thus it becomes imperative to provide to the operator of the system a means for assessing the system's output and specifically a means to assess the biological consequences of that increased output. The Output Display Standard (AIUM/NEMA, 1992) does this, in part, by providing calculated quantities which are based on biophysical indicators, namely, an index which relates to the maximum tissue temperature increase in the beam (the Thermal Index) and an index which relates to the potential for producing cavitation (the Mechanical Index).

When the Food and Drug Administration initiated the regulation of diagnostic ultrasound equipment in the mid-1980s (FDA, 1985), it set application-specific intensity limits which manufacturers could not exceed (see Table 1). Note that for the Fetal Imaging and Other application, the spatial peak, temporal average intensity could not exceed 94 mW/cm². These limits were not based on safety considerations. Rather, they were based on the output of diagnostic ultrasound equipment at the time when the Medical Devices Amendments were enacted, in May, 1976.

Diagnostic ultrasound manufacturers can still have their equipment approved through the application-specific limits listed in Table 1. However, now, manufacturers can also have their equipment approved under the provisions of the Output Display Standard (AIUM/NEMA, 1992; FDA, 1993, 1994) in which case the regulatory upper limits are based on the spatial peak, temporal average intensity, \( I_{SPTA} \), of 720 mW/cm² and the Mechanical Index, \( MI \), of 1.9. In doing so, provisions must be made available for the Thermal Index, \( TI \), and \( MI \) to be displayed. The following discussion describes the meaning of these indices and the conditions under which they are displayed.

<table>
<thead>
<tr>
<th>Derated Intensity Values</th>
<th>( I_{SPTA} )</th>
<th>( I_{SPPA} )</th>
<th>( I_m )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac</td>
<td>430</td>
<td>190</td>
<td>310</td>
</tr>
<tr>
<td>Peripheral Vessel</td>
<td>720</td>
<td>190</td>
<td>310</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>17</td>
<td>28</td>
<td>50</td>
</tr>
<tr>
<td>Fetal Imaging and Other*</td>
<td>94</td>
<td>190</td>
<td>310</td>
</tr>
</tbody>
</table>

* Abdominal, Intraoperative, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic

OUTPUT DISPLAY STANDARD

The purpose of the Output Display Standard (AIUM/NEMA, 1992) is to provide the capability for users of diagnostic ultrasound equipment to operate their systems at levels much higher than previously had been possible in order to have greater diagnostic capabilities. In doing so, the possibility exists for the potential to do harm to the patient. Therefore, two biophysical indices are provided so that the equipment operator has real-time information available to make appropriate clinical decisions, viz., benefit vs. risk, and to implement the ALARA (As Low As Reasonable Achievable) principle.
The Output Display Standard was developed over a period of about three years and involved clinicians, scientists, engineers and government regulators from many organizations (see Table 2).

Table 2: Organizations involved in the development of the Output Display Standard

PROFESSIONAL SOCIETIES
- American Academy of Neurology
- American Academy of Ophthalmology
- American Association of Physicists in Medicine
- American College of Cardiology
- American College of Osteopathic Obstetrics & Gynecology
- American College of Radiology
- American Institute of Ultrasound in Medicine
- American Registry of Diagnostic Medical Sonographers
- International Perinatal Doppler Society
- National Council on Radiation Protection
- Society of Diagnostic Medical Sonographers
- Society of Pediatric Echocardiography
- Society of Perinatal Obstetricians
- Society of Vascular Technology
- World Federation for Ultrasound in Medicine & Biology

CONSUMER GROUPS
- International Childbirth Education Association
- National Women's Health Network

NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

FOOD AND DRUG ADMINISTRATION'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Two basic indices are required, viz., the Thermal Index and the Mechanical Index. Specifically, three Thermal Indices and one Mechanical Index are required, each of which are described.

THERMAL INDEX

Table 3 describes the three Thermal Indices for the three different tissue models and two scan modes. They are termed, along with their abbreviations, as follows:

TIS: Soft Tissue Thermal Index
TIB: Bone Thermal Index
TIC: Cranial Bone Thermal Index

Table 3: Outline of the three Thermal Indices

<table>
<thead>
<tr>
<th></th>
<th>Scanned Mode</th>
<th>Unscanned Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft Tissue</td>
<td>TIS at Surface</td>
<td>TIS Small Aperture</td>
</tr>
<tr>
<td>Bone at Focus</td>
<td>TIS at Surface</td>
<td>TIB</td>
</tr>
<tr>
<td>Bone at Surface</td>
<td>TIC</td>
<td>TIC</td>
</tr>
</tbody>
</table>

The basic definition of all Thermal Indices is

\[
TI = \frac{W_o}{W_{DEG}}
\]  

(11)

where \(W_o\) is the source power of the diagnostic ultrasound system and \(W_{DEG}\) is the source power required to increase the tissue temperature 1°C under very specific and conservative conditions. Tissue perfusion was included in the development of the \(W_{DEG}\) expressions.

Tissue Models

Three tissue models were considered (see Figures 1-3). Figure 1 is typical of a scanning condition in which there is only soft tissue in the sound beam path. The assumption is that the soft tissue is homogeneous (in terms of both acoustic and thermal properties) with an attenuation coefficient (also referred to as a derating factor) of 0.3 dB/cm-MHz.

![Homogeneous Soft Tissue Model](image)

Figure 1: Homogeneous soft tissue model
Figures 2 and 3 consider two cases in which bone is within the sound beam path. The bone at the focus tissue model is typical of second and third trimester fetal imaging in which fetal bone may be intercepted by the sound beam (see Figure 2). Here, the interposed tissue is assumed to have the same homogeneous properties as the soft tissue model. The bone at the surface tissue model is typical of adult cephalic imaging (see Figure 3).

![Figure 2: Bone at focus tissue model](image)

![Figure 3: Bone at surface tissue model](image)

**Scanning Modes**

Both scanned and unscanned modes are considered in the development of the $W_{DEG}$ expressions for the estimate of the appropriate Thermal Indices (see Figure 4).

![Figure 4: Scanned (top) and unscanned (bottom) modes](image)

**TIS at Surface**

Figure 5 shows a typical axial temperature increase profile for the homogeneous soft tissue model under scanned mode conditions. Note that the maximum temperature increase occurs near the surface, usually within the first couple of centimeters of the skin surface.

![Figure 5: Axial temperature increase profile for the bone at focus tissue model and scanned mode](image)

Figure 6 shows a typical axial temperature increase profile for the bone at focus tissue model under scanned mode conditions. Note that the maximum temperature increase also occurs near the surface, usually within the first couple of centimeters of the skin surface. The same $TIS$
calculation is made for $W_{\text{DEG}}$ for both conditions shown in Figures 5 and 6. The $TIS$ calculation estimates the Thermal Index at the location where the temperature increase is a maximum value, viz., at the surface.

**Figure 6:** Axial temperature increase profile for the bone at focus tissue model and scanned mode

**TIC**

Figure 7 shows a typical axial temperature increase profile for the bone at surface tissue model under scanned mode conditions. Note that the maximum temperature increase occurs at the bone surface.

**Figure 7:** Axial temperature increase profile for the bone at surface tissue model and scanned mode

Figure 8 shows a typical axial temperature increase profile for the bone at surface tissue model under unscanned mode conditions. Note that the maximum temperature increase also occurs at the bone surface. The same $TIC$ calculation is made for $W_{\text{DEG}}$ for both conditions shown in Figures 7 and 8. The $TIC$ calculation estimates the Thermal Index at the location where the temperature increase is a maximum value, viz., at the adult cranial bone surface.

**TIB**

**Figure 8:** Axial temperature increase profile for the bone at surface tissue model and unscanned mode

not at the skin surface although there is an increase in temperature there also. The $TIB$ calculation estimates the Thermal Index at the location where the temperature increase is a maximum value, viz., at the second or third trimester fetal bone.
where \( p_{r.3} \) is the derated peak rarefactual pressure (see Figure 11) in MPa (megapascals) and \( f \) is the ultrasonic frequency in MHz. The derating factor (attenuation coefficient of soft tissue) is assumed to be 0.3 dB-cm-MHz. The \( MI \) represents the potential for cavitation in tissue although there has never been a reported case where cavitation has been known to occur from scanning a patient with diagnostic ultrasound equipment. The index is based on theoretical and laboratory experiments.

**MECHANICAL INDEX**

The Mechanical Index, \( MI \), is defined as

\[
MI = \frac{p_{r.3}}{\sqrt{f}}
\]  
(12)

**DISPLAY REQUIREMENTS**

If the diagnostic ultrasound equipment is capable of equaling or exceeding a \( TI \) of 1, then the appropriate \( TI \) (\( TIS, TIC, TIB \)) must be displayed in increments of no more than 0.2 for indices less than 1 and in increments of 1 or less for indices equal to or greater than 1.

If the diagnostic ultrasound equipment is capable of equaling or exceeding an \( MI \) of 1, then the appropriate \( MI \) must be displayed in increments of no more than 0.2 for indices less than 1 and in increments of 1 or less for indices equal to or greater than 1.
Figure 11: Typical acoustic pressure waveform which shows the peak compressional pressure ($p_c$) and peak rarefactual pressure ($p_r$).

In those cases where indices must be displayed and the specific index is less than 1, the index must be displayed from a value of 0.4. This allows the system operator to know when the appropriate index is approaching a critical value, say around 1, and then make the appropriate clinical decision.

All indices do not have to be displayed at the same time.

- The $MI$ need only be displayed when the system is operating in B-mode imaging only.
- The $TIS$ and $TIB$ need not be displayed at the same time during an obstetrical examination but the system must have the capability for the operator to choose between the two indices to be displayed.
- The $TIC$ must be provided when the system is intended solely for adult cephalic application.

The system must also have the capability to display the appropriate indices under combined modes of operation. This applies to the Thermal Indices where multiple modes of operation can produce a summation of heating from each mode.

ACKNOWLEDGMENTS

The author gratefully acknowledge support from NIH grant CA09067.

REFERENCES


